

## **Remarks**

### **Status of the Claims**

Claims 1-52 are pending in this application.

Reconsideration of the final rejection of the claims is respectfully requested.

### **Amendments to the Specification**

The specification is amended herein to correct a typographical error.

### **Allowable Subject Matter**

Claims 44-48 were objected to as dependent upon a rejected base claim and indicated to be allowable if rewritten in independent form. However, claim 44 is independent as currently written. Applicant requests that the objection to claims 44-48 be withdrawn as these claims recite allowable subject matter.

### **Claim Rejections under 35 U.S.C. §103**

Claims 1-6, 10-15, 18, 20, 21, 24-28, 31-41, and 49-51 have been rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 3,983,873 (Hirschman). Applicant traverses and expressly reserves the right to appeal this rejection. Claims 1-6, 10-15, 20, 21, 24-28, 31-41, and 49-51 are not obvious over Hirschman. Hirschman fails to teach each and every element present in claims 1-6, 10-15, 20, 21, 24-28, 31-41, and 49-51 as is required for a *prima facie* case of obviousness (M.P.E.P. § 2143.03) and therefore cannot anticipate or render obvious any of these claims.

As was stated in the Applicant's Amendment and Response submitted October 2, 2006 (the prior Response), Hirschman teaches an interlabial pad useful for collecting urine or vaginal discharge from a subject. (see col. 2, line 46-51). The Office has admitted that Hirschman does not teach a method for absorbing leakage from a subject's anus or a method for treating a symptom of a subject with hemorrhoids. The prior Response clearly indicates where Hirschman is deficient in disclosing each and every claim element. These deficiencies appear to have been overlooked as they were not addressed in the current Office action. The Office purports to have fully considered the arguments

presented in the prior Response but considers them unpersuasive offering the following explanation (page 2, first paragraph); “a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentable distinguish the claimed invention from the prior art.” This argument fails to rebut the Applicant’s position because the claims at issue do not recite an intended use of the claimed invention, but rather steps of a method.

For example, claim 1 recites a “method for absorbing leakage from an anus of a subject, comprising positioning an intergluteal absorbent pad external to the subject's anal orifice.” Hirschman is silent as to positioning an intergluteal absorbent pad external to the subject's anal orifice. Furthermore, the two cases cited by the Office in support of its position (*In re May*, 574 F.2d 1082, 1090, 197 USPQ 601 (CCPA 1978); *In re Tomlinson*, 363 F.2d 928, 150 USPQ 623 (CCPA 1966)) are not relevant to the claims at issue. Both cases concern newly discovered latent properties of chemical compounds. The disputed claims of *In re May* and *In re Tomlinson* do not recite novel steps of a method, but attempt to claim the latent properties in the preamble of the claim. The claims in question in the current application (claims 1-6, 10-15, 20, 21, 24-28, 31-41, and 49-51) are directed to methods that include steps not disclosed by Hirschman. These claims are not directed to latent properties of an old composition and therefore the cited cases do not apply.

Positively recited method steps in a claim must be considered when evaluating patentability. The Office must examine a claim as written (a method for absorbing leakage from an anus of a subject by positioning an intergluteal pad external to the subject’s anal orifice such that the pad is retained between the buttocks). The Office action instead appears to have assumed the claim is to a pad and then rejected the claim based on that unwarranted assumption. In contrast, the references are utterly devoid of any disclosure of the steps of the claimed method; a *prima facie* case of obviousness has therefore not been established.

Even if claims 1-6, 10-15, 20, 21, 24-28, 31-41, and 49-51 did merely recite an intended use of the claimed invention, which Applicant in no way admits, the invention as recited in these claims fulfills the Office’s perceived requirement of a structural difference between the claimed invention and

the prior art. All of the pending claims require positioning an intergluteal absorbent pad external to the subject's anal orifice. As an example, claim 1 recites a method which includes the step of "positioning an intergluteal absorbent pad external to the subject's anal orifice such that the pad is retained between the buttocks," (emphasis added). In marked contrast, Hirschman discloses "feminine hygiene pads for placement in the interlabial space" (column 1, lines 20-22, emphasis added). The labia and buttocks are not identical anatomical structures. The specification at page 7, fourth paragraph defines the intergluteal space as "[t]he space located between the right and left gluteals (buttocks), generally on a sagittal plane that includes the anus. The intergluteal space extends inferiorly toward the perineal body to the vaginal opening in the female (but does not include the vaginal opening)" (emphasis added). This is clearly illustrated in Figures 1 and 2 provided in Exhibit A. Exhibit A, Figure 1 shows the position of an intergluteal pad as is recited in claims 1-6, 10-15, 20, 21, 24-28, 31-41, and 49-51, wherein the intergluteal pad 30 is retained between the buttocks adjacent to the anal orifice 32. This is contrasted with the placement of the interlabial pad as shown in Exhibit A, Figure 2. The interlabial pad 30 is positioned in the interlabial space 32 adjacent the labia majora 34, vaginal orifice 38, and urethral orifice 40. As illustrated in Exhibit A, the position of the intergluteal pad clearly results in a structural difference between the claimed method and the method disclosed by Hirschman, namely positioning of the pad with respect to the buttocks instead of the labia. There is no disclosure or teaching in the cited references to perform this positively recited step.

For the above reasons and those stated in the prior Response, the Office has not presented a *prima facie* case of obviousness with respect to claims 1-6, 10-15, 20, 21, 24-28, 31-41, and 49-51. The cited references fail to establish a *prima facie* case of obviousness because they do not disclose the method step of positioning an intergluteal absorbent pad external to the subject's anal orifice. Therefore, these claims are allowable and Applicant requests that the rejection be withdrawn.

Claims 7-9, 19, 22, 23, 42, and 43 have been rejected under 35 U.S.C. §103(a) as allegedly being obvious over Hirschman in view of U.S. Patent No. 5,074,855 (Rosenbluth). Applicant traverses and expressly reserves the right to appeal this rejection. At least three basic requirements must be met to establish a *prima facie* case of obviousness. First, the Office must show how the prior art references teach each and every limitation of the claims. M.P.E.P. § 2143.03. The Office must also establish that

there was motivation in the prior art to modify the reference or combine the teachings to produce the claimed invention. M.P.E.P. § 2143.01. Finally, the Office must demonstrate that the prior art supports a reasonable expectation of success for achieving the invention. M.P.E.P. § 2143.02. The Office has failed to meet these requirements with respect to claims 7-9, 19, 22, 23, 42, and 43 and they are allowable.

Claims 7-9, 19, 22, 23, 42, and 43 are not obvious over Hirschman in view of Rosenbluth *et al.* For the reasons stated above and those presented in the prior Response, Hirschman does not teach each and every element of claims 7-9, 19, 22, 23, 42, and 43, namely positioning a pad such that the pad is retained between the buttocks. This deficiency is not overcome by combining Hirschman with Rosenbluth *et al.* Rosenbluth is silent on positioning a pad such that it is retained between the buttocks. Therefore, the combination of Hirschman with Rosenbluth *et al.* does not teach each and every claim element and cannot render claims 7-9, 19, 22, 23, 42, and 43 obvious (M.P.E.P. § 2143.03).

Moreover, as pointed out in the prior Response, the Office has failed to establish a *prima facie* case of obviousness because it has not established that there is a suggestion or motivation to modify the references to yield the claimed method (see M.P.E.P. § 2143.01). In fact, the references themselves teach away from the proposed combination of Hirschman and Rosenbluth *et al.*, because Rosenbluth explicitly states that use of the absorbent pad of Hirschman is to be avoided (Rosenbluth *et al.* at col. 1, lines 60-61 specifically identifies Hirschman U.S. Pat. No. 3,983,873 as the disadvantageous prior art in which absorbent pads absorb liquid discharges). One skilled in the art would not modify the absorbent pad of Hirschman using a reference that teaches that the absorbent pad of Hirschman is to be avoided. The Office cannot pick and choose details of Rosenbluth *et al.* while ignoring the explicit warnings of Rosenbluth *et al.* not to use them in a pad that absorbs liquid discharges.

The cited references also do not disclose a method for providing a diagnostic or therapeutic agent on an intergluteal pad, as recited in claims 8-9, 22-23, and 42-43. The Office action appears to assert that it would be obvious to provide a therapeutic agent in an interlabial pad and therefore the

method is obvious. Such a rejection overlooks the requirement that a *prima facie* case of obviousness must be established with respect to the claimed method, in which the pad is positioned against the anus. Since the cited references are devoid of any such suggestion, a *prima facie* case of obviousness has not been established with respect to the claims.

In addition, the device disclosed by Rosenbluth *et al.* is a urethral meatus occlusion device (abstract, lines 1-3) “to be retained in place by adhesion to at least a part of the anatomical structure of the external female genitalia” (Rosenbluth *et al.*, col. 2, lines 29-30). One of ordinary skill in the art reading the Rosenbluth *et al.* disclosure would not be motivated to modify the Rosenbluth *et al.* reference to be retained between the buttocks. Modification of the Rosenbluth *et al.* device and methods would render the device unworkable for its intended purpose, which is to provide occlusion of the urethral meatus. A *prima facie* case of obviousness cannot be established where the proposed modification renders the prior art unworkable (M.P.E.P. § 2143.03 VI).

For the above reasons and those stated in the prior Response, the Office has not presented a *prima facie* case of obviousness with respect to claims 7-9, 19, 22, 23, 42, and 43. Therefore, these claims are allowable, and Applicant requests that the rejection be withdrawn.

Claims 16, 17, 29, and 30 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Hirschman in view of U.S. Patent No. 4,920,045 (Okuda). The Office action asserts that it would be obvious to modify the interlabial pad of Hirschman to perform a diagnostic test on fecal material, because Okuda discloses that occult blood can be detected in feces. However, the only suggestion for modifying Hirschman to provide an intergluteal pad against the anus, and performing a diagnostic test on anal discharge comes from the Applicant’s own specification. The cited references are completely devoid of any such suggestion. In the absence of a disclosure and motivation in the prior art to perform a diagnostic test on an anal pad, a *prima facie* case of obviousness has not been made. The *prima facie* case must come from the references themselves instead of from impermissible hindsight reconstruction on the invention in view of the Applicant’s own disclosure. Nowhere in the cited references is the claimed diagnostic method suggested.

For the above reasons and those stated in the prior Response, the Office has not presented a *prima facie* case of obviousness with respect to claims 16, 17, 29, and 30. Therefore, these claims are allowable, and Applicant requests that the rejection be withdrawn.

Claims 51 and 52 have been rejected under 35 U.S.C. §103(a) as allegedly being obvious over Hirschman in view of U.S. Patent No. 6,967,025 (Di Cintio). Applicant traverses and expressly reserves the right to appeal this rejection.

Claims 51 and 52 are rejected over Hirschman in view of Di Cintio. The Office contends that it would have been obvious to modify the pad disclosed by Hirschman to include the odor control agents disclosed by Di Cintio. Hirschman is completely silent about a method for absorbing leakage from an anus of a subject. Hirschman also does not teach positioning a pad such that it is retained between the buttocks. These deficiencies are not made up by Di Cintio. Di Cintio does not teach positioning a pad between the buttocks. Therefore, the cited references fail to teach each and every claim limitation and cannot render the claims obvious.

For the above reasons and those stated in the prior Response, the Office has not presented a *prima facie* case of obviousness with respect to claims 51 and 52. Therefore, these claims are allowable, and Applicant requests that the rejection be withdrawn.

### **Conclusion**

A *prima facie* case of obviousness has not been established by the Office action because the claimed subject matter is not disclosed or suggested by the cited references. Multiple elements of the method claims are absent from the cited references, and the Applicant's own disclosure can not be used in a hindsight reconstruction of the claimed method. A *prima facie* rejection of a method claim cannot be established by citing references that are literally devoid of any mention of the claimed method step of positioning an intergluteal absorbent pad external to the anal orifice, such that it is retained between the buttocks to absorb discharge. Even if these features had been disclosed in the references (which they are not), there is no motivation within the references to produce the claimed invention. Applicants request that the rejections of the claims be reconsidered and withdrawn.

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